Zemplar (**P12-269)** Study

User's Manual
V2.1

http://zemplar.planimeter.hu

Study protocol (1)

This is a non-interventional, observational, open-label, multi-country, multicenter post-marketing study in which Zemplar is prescribed in the usual manner in accordance with the terms of the local market authorization with regards to dose, population and indication.

All patient data entered in the patient's case report form (CRF) will be forwarded - without naming the patient - for evaluation to Abbott. In order to maintain patient confidentiality, instead of date of birth, the patient's year of birth will be documented in the CRF.

Inclusion Criteria

1) Patients ≥ 18 years

2) Patients with CKD stage 3 or 4 and also has SHPT

3) Patients with iPTH > 70 pg/ml and with CKD stage 3 or with

4)iPTH > 110 pg/ml and with CKD stage 4

5) Patients clinically indicated for the treatment with Zemplar cps

6) Patient must provide the authorization to use his/her data for statistical evaluation before entering to the PMOS. Local Law requirements to be followed.

Exclusion Criteria

1) Patients with clinically important hypercalcemia =Ca> 2.6 mmol/l (10.5 mg/dL)
2) Patients suffering from proven intoxication of vitamin D or patient with proven hypersensitivity of paricalcitol or any other part of the product

User Activation

P12-269 eCRF
3)
Home
User activation
Help
User activation
Zemplar eCRF does not allow open registration for users. The participators were all assigned pre-registered usersnames.
In order to start working in Zemplar eCRF, these usernames have to be activated first. The username defined for each user co
E-mail address (for example, if you were registered with "abcdef@ghi.jk" as E-mail address, your username is "abef").
Please fill out the form below.
4)
Username :
Activate user
5)
Home
User activation
Help
Copyright ® 2010 Planimeter.hu

1) If you are a **contracted physician** of this study, please provide your e-mail address to the sponsor

2) Then you will receive e-CRF link from the service provider (Planimeter Kft.).

3) Click on the link

4) Choose the "User Activation" tab

5) Follow the instructions on the page and give your username

6) Click the "Activate User" button.

Login the system at first time

1) Choose the “Home” tab

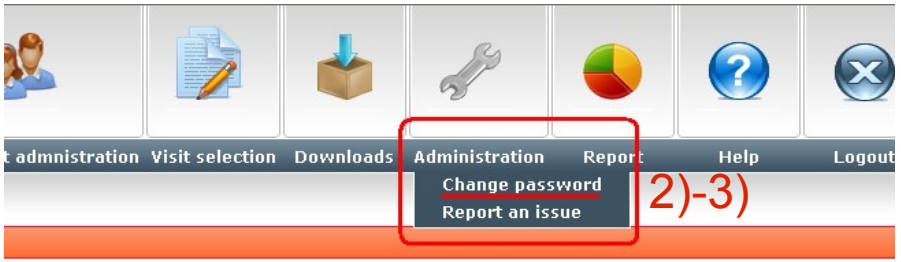
2) Type your username into the “Username” box

3) Type the password you got in an e-mail AFTER activating your username

4) Click the “Login” button

Password management

Password can be changed anytime after username activation. Any password should contain at least 6 characters, can not contain any other symbol than the letters of English alphabet or numbers but can not start with number.

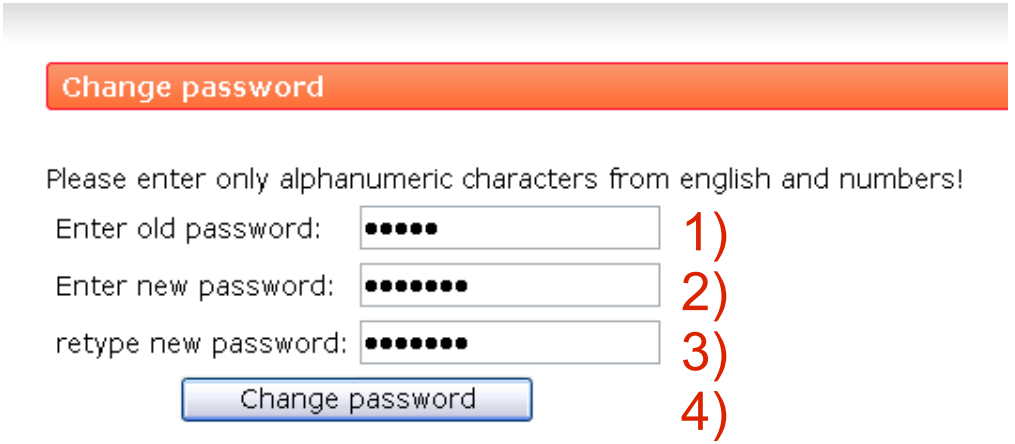


1) Changing the password after the first login is recommended but not obligatory.

2) To change the password, choose the “Administration” tab.

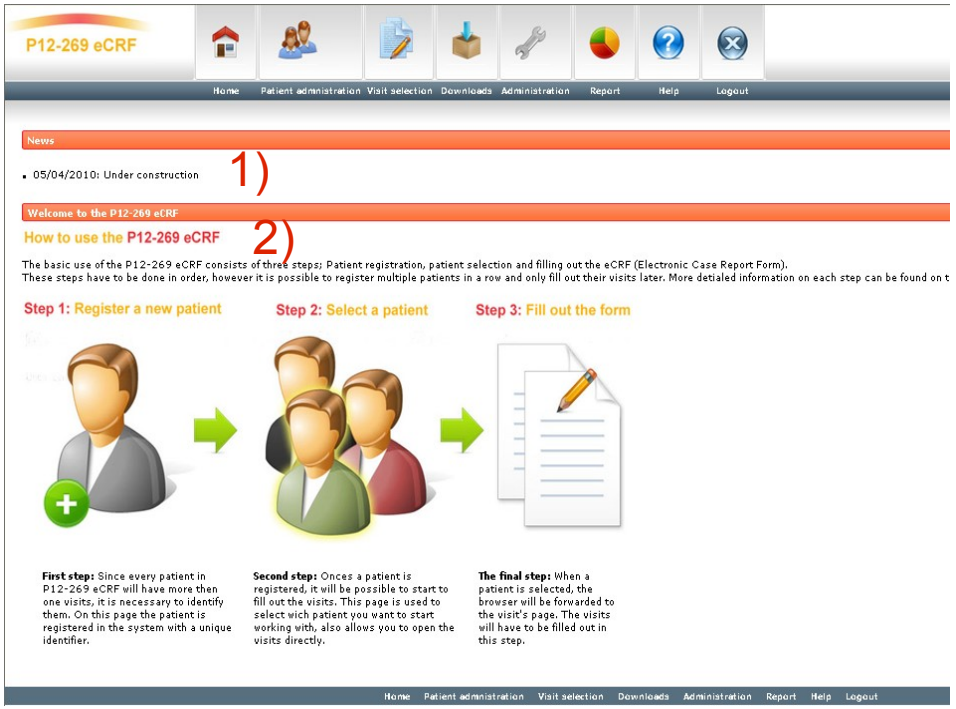
3) Choose the “Change password” option and follow the instructions.

Password management (2)



1) Type your old (still valid) password
2) Type a new password, do not forget the general rules (English alphabet / digits and min. 6 characters). IMPORTANT: small and capital letters are DIFFERENT
3) Re-type the new password.
4) Click the “Change password“ button.

Home

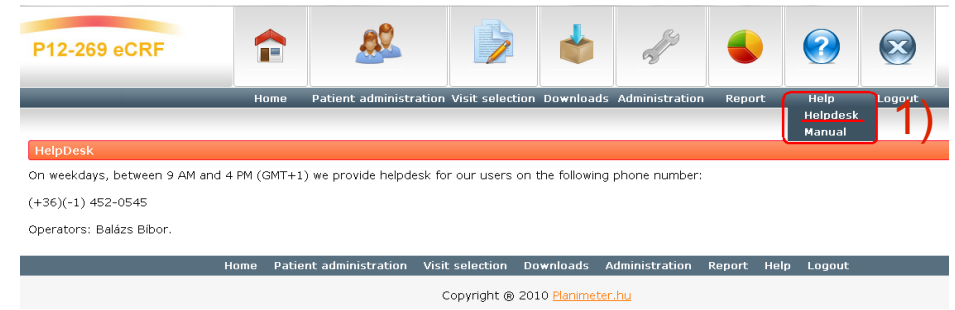

P12-269 eCRF
Home
Patient administration
Visit selection
Downloads
Administration
Report
Help
Logout
News
05/04/2010: Under construction
1)
Welcome to the P12-269 eCRF
How to use the P12-269 eCRF
2)
The basic use of the P12-269 eCRF consists of three steps; Patient registration, patient selection and filling out the eCRF (Electronic Case Report Form).
These steps have to be done in order, however it is possible to register multiple patients in a row and only fill out their visits later. More detialed information on each step can be found on t
Step 1: Register a new patient
Step 2: Select a patient
Step 3: Fill out the form
First step: Since every patient in P12-269 eCRF will have more then one visits, it is necessary to identify them. On this page the patient is registered in the system with a unique identifier.
Second step: Onces a patient is registered, it will be possible to start to fill out the visits. This page is used to select wich patient you want to start working with, also allows you to open the visits directly.
The final step: When a patient is selected, the browser will be forwarded to the visit's page. The visits will have to be filled out in this step.
Home
Patient administration
Visit selection
Downloads
Administration
Report
Help
Logout

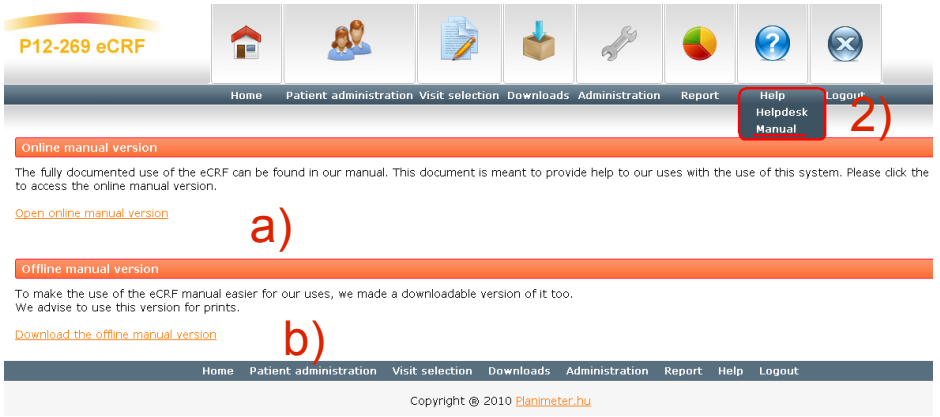
The “Home” page – as usual – is the center of the navigation. You can reach here:

1) News, announcements concerning the Study and/or the eCRF.

2) A short description of the eCRF processing

Help




P12-269 eCRF
Home
Patient administration
Visit selection
Downloads
Administration
Report
Help
Helpdesk
Manual
Logout
2)
Online manual version
The fully documented use of the eCRF can be found in our manual. This document is meant to provide help to our uses with the use of this system. Please click the to access the online manual version.
Open online manual version
a)
Offline manual version
To make the use of the eCRF manual easier for our uses, we made a downloadable version of it too.
We advise to use this version for prints.
Download the offline manual version
b)
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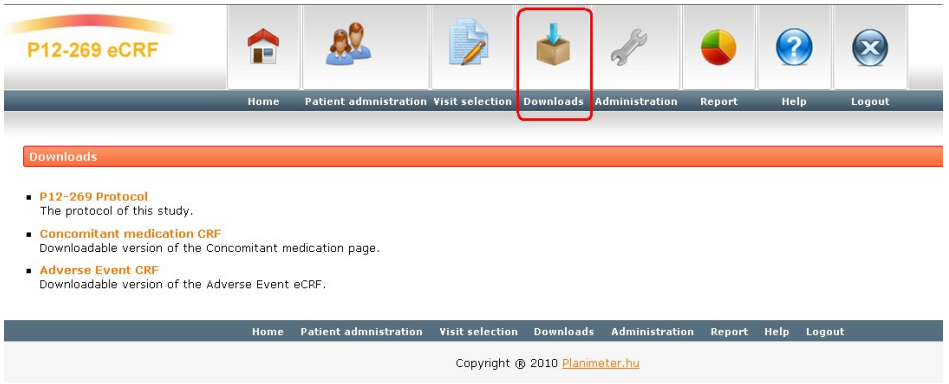
You have two choices under Help

1) Helpdesk – you can find a telephone number here, which can be used to contact our Helpdesk between 9 AM and 4 PM (GMT+1).

   If your call is not answered, please leave a message containing your username, protocol number, E-mail address and the full description of the problem.

2) Manual – The are two versions of the Manual;
   a) online version (html)
   b) offline version (pdf)

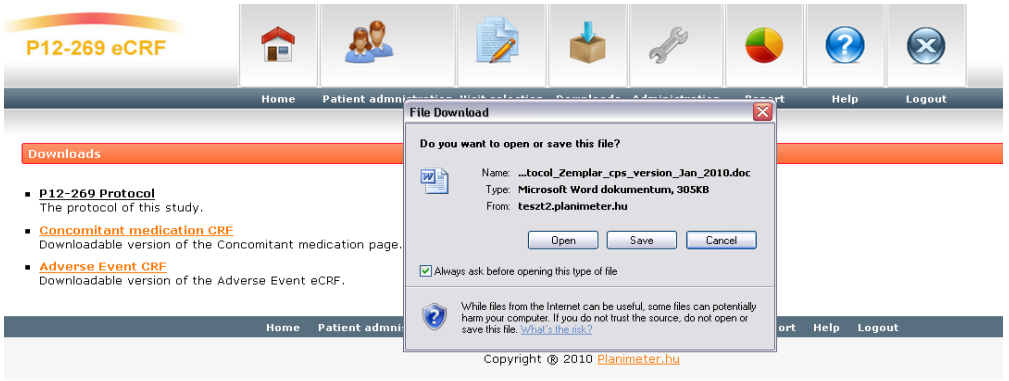
Downloads



The documents of the Study to be downloaded are available under the “Downloads” menu item. If you want extra documents to be placed here, contact your country PMOS coordinator.

- Protocol of the Study
- Concomitant medication page
- Adverse Event Page

Downloads (2)


P12-269 eCRF
Home
Patient administration
Visit selection
Downloads
Administration
Report
Help
Logout
Downloads
P12-269 Protocol
The protocol of this study.
Concomitant medication CRF
Downloadable version of the Concomitant medication page.
Adverse Event CRF
Downloadable version of the Adverse Event eCRF.
File Download
Do you want to open or save this file?
Name: ...tocol_Zemplar_cps_version_Jan_2010.doc
Type: Microsoft Word dokumentum, 305KB
From: teszt2.planimeter.hu
Open
Save
Cancel
Always ask before opening this type of file
While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. What's the risk?
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1) By clicking a document's name, a message box will appear offering the possibility of direct opening of the document or saving the document for further use.

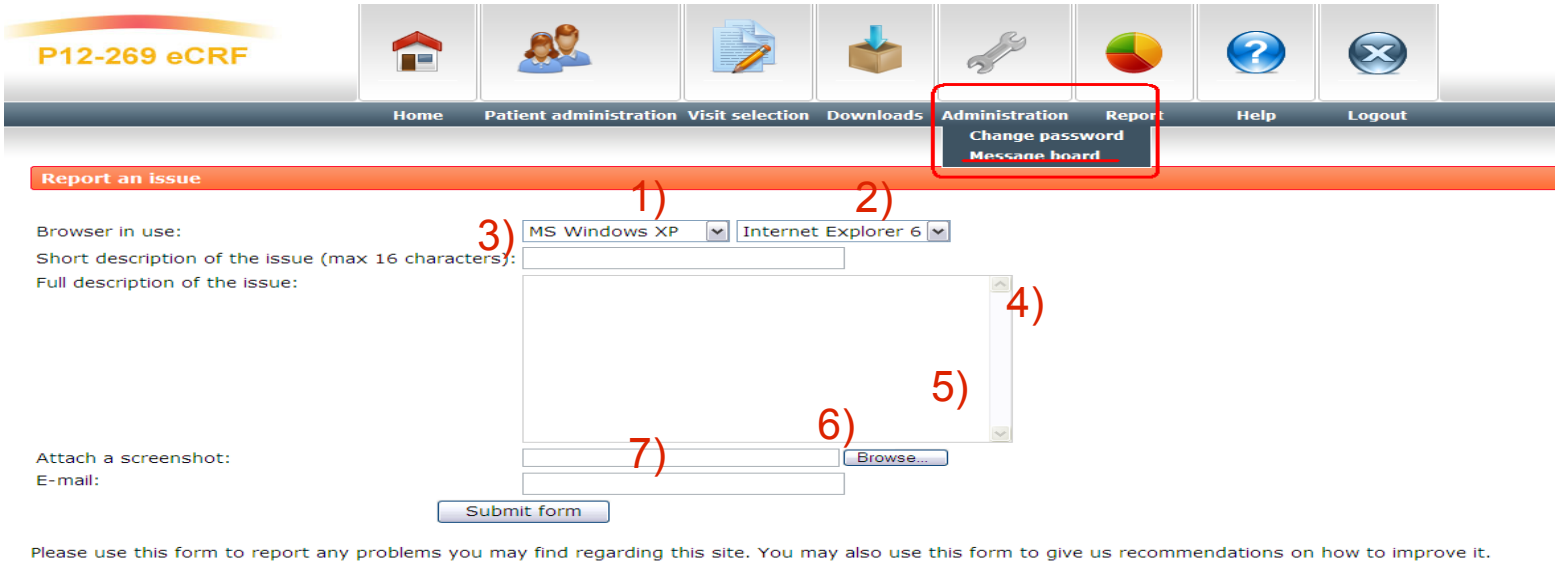
Reporting of errors, remarks

There is an option to indicate malfunction of the eCRF system to the developers directly via the menu item “Message board”.

To send a message or remark to the Planimeter developers, please choose the “Administration” menu item from the main menu and then choose the “Message board” option.

The reported phenomena will be investigated and commented through this system as well.

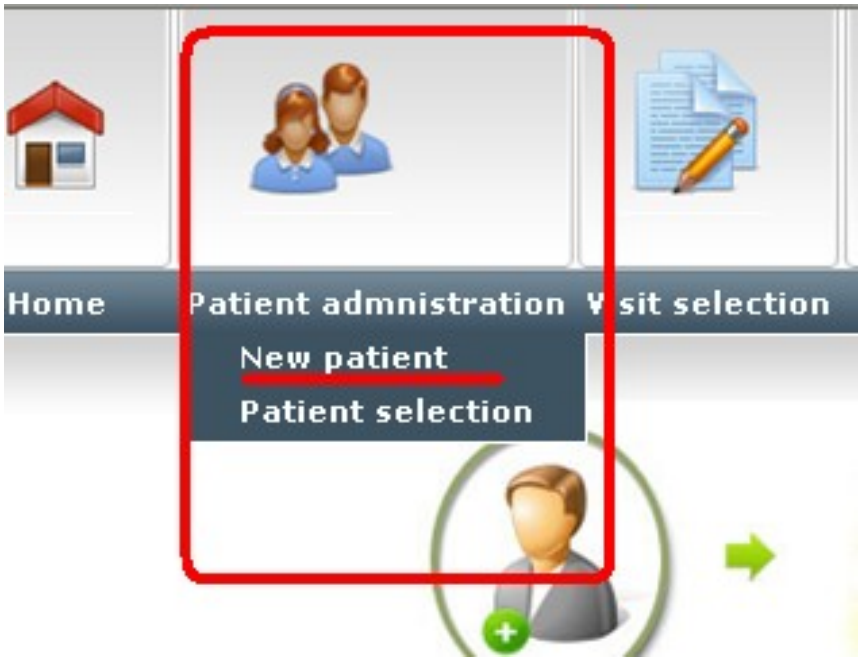
Reporting of errors, remarks (2)



Please give or type:

1) The name and version of the operation system of your PC.
2) The name and the version number of the web-browser you used when the error/problem occurred. The version number of the web-browser generally can be reached under the “Help” menu item of the WEB-BROWSER
3) A short title of your remark or the reported error
4) A short description of the error, or malfunction
5) There is a place to attach a screenshot (BMP or JPEG format is preferred). This step is optional.
6) Your e-mail address
7) Finally click the “Submit form” button.

Enrollment of a New Patient

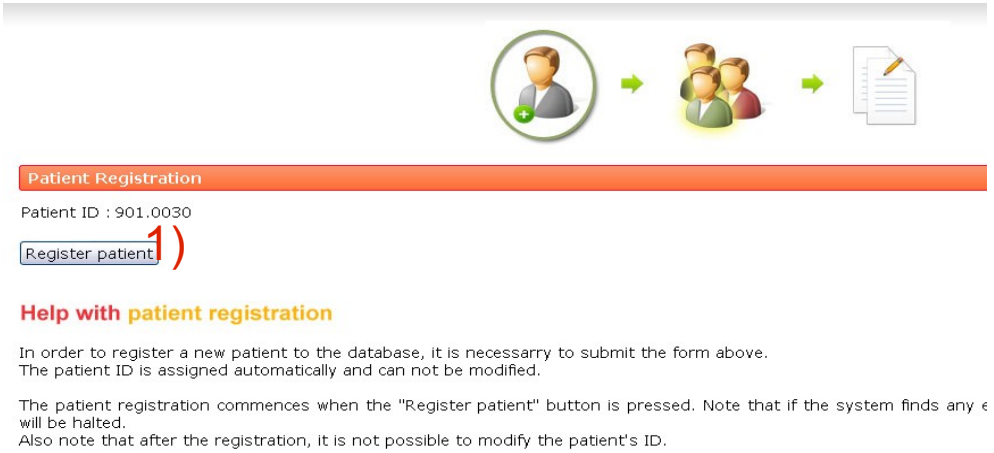


If you would like to enroll a new patient in the Study, please choose the “Patient administration” menu item and then click the “New patient” menu item.

After the enrollment, a new form is created with a patient ID like XXX.XXXX . The first three digits of the Patient ID is the center ID, while the last four digits form a number, which starts with 1 in each center.

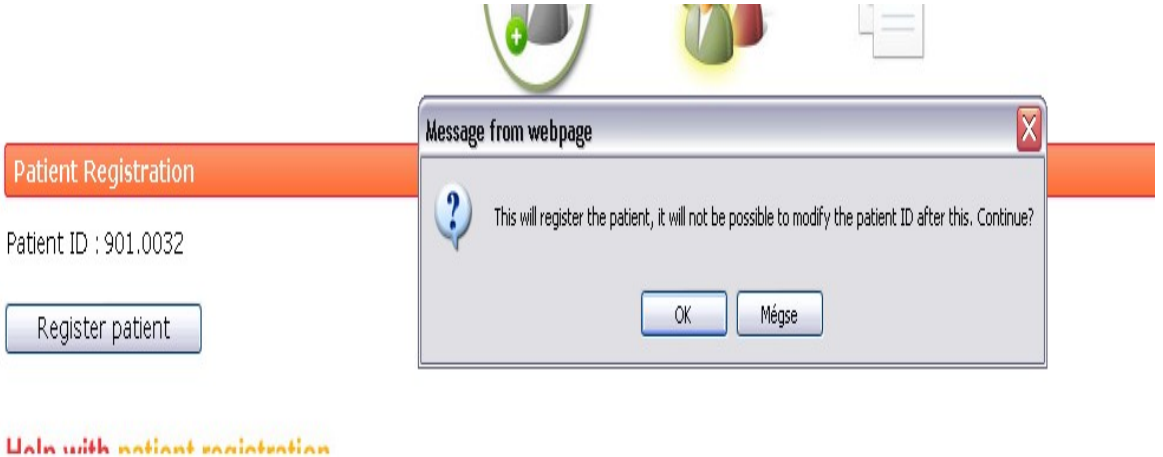
There is no way to modify the Patient ID during the Study.

Enrollment of a new patient (2)


Patient Registration
Patient ID : 901.0030
Register patient
1)
Help with patient registration
In order to register a new patient to the database, it is necessarry to submit the form above.
The patient ID is assigned automatically and can not be modified.
The patient registration commences when the "Register patient" button is pressed. Note that if the system finds any
will be halted.
Also note that after the registration, it is not possible to modify the patient's ID.

1) The Patient ID is given automatically by the eCRF program. Please click “Register patient” button.

Enrollment of a new patient (3)


Patient Registration
Patient ID : 901.0032
Register patient
Message from webpage
This will register the patient, it will not be possible to modify the patient ID after this. Continue?
OK
Mégse

After clicking the “Register patient” button a message box will appear.

Enrollment of a new patient (4)

P12-269 eCRF
Home
Patient admnistration
Visit selection
Downloads
Administration
Report
Help
Patient Registration
"901.0026" patient ID registered!
Click here to go to patient selection screen
Click here to register another patient
1)
Help with patient registration
In order to register a new patient to the database, it is necessarry to fill out the form above.
The patient's verbal or signed informed consent has to be filled out. The patient ID is filled out automatically and can not be modified.
Onces the form has been filled out, the patient registration commences when the "Register patient" button is pressed. Note that if the sys
(invalid ID or date), registration will be halted.

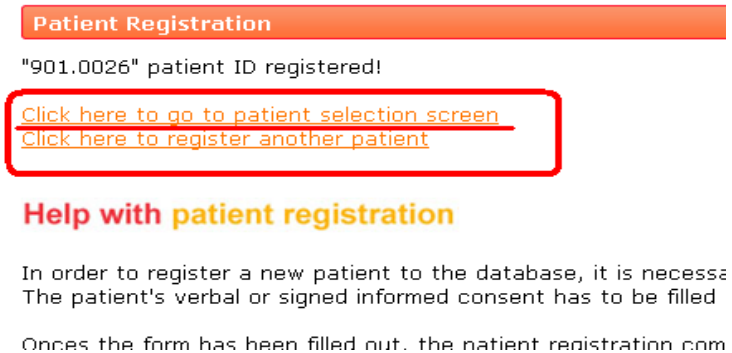
After enrollment of a new patient, you can continue

1) with the enrollment of further new patients (by choosing the “Click here to register another patient”)

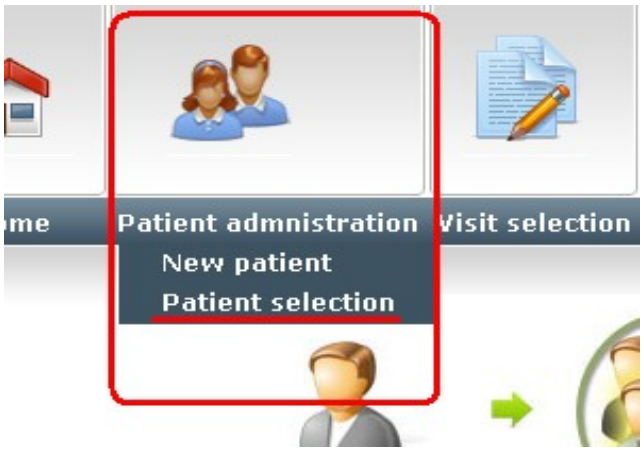
or

2) Typing further data of the already enrolled patient(s) (by choosing “Click here to go to patient selection screen”)

Patient selection


Patient Registration
"901.0026" patient ID registered!
Click here to go to patient selection screen
Click here to register another patient
Help with patient registration
In order to register a new patient to the database, it is necessa
The patient's verbal or signed informed consent has to be filled

1)



2)

Further editing of Visit data can be reached after Patient (and visit) selection.

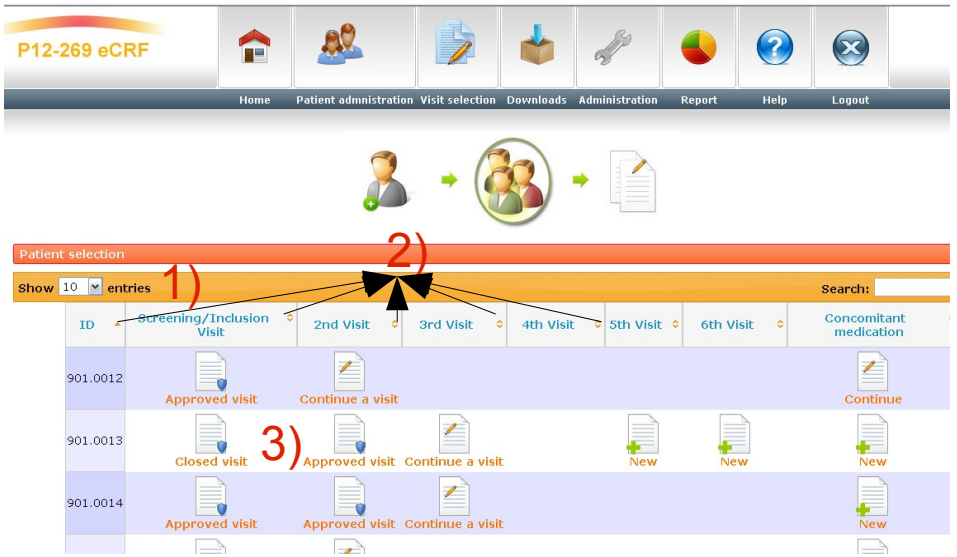
You can reach the Patient selection panel by

1) choosing the menu item “Click here to go to patient selection screen” after inclusion of a new patient (see previous pages)

   or

2) choosing the “Patient selection” option under the main menu's Patient administration menu item.

Patient selection (2)



1) You can give here the number of rows you would like to see on one screen.

2) You can order the table into increasing or decreasing order with clicking the small arrows in the columns.

3) You can choose the required Visit by clicking the suitable visit icon in the row of the required patient.

Definition of the Visit status

1) „Start new visit“: this is an empty visit. No data has been entered yet.

2) „Continue a visit“: this is a saved visit. There are some entered data, and these data are stored on the server. The visit can be re-opened and all the data are available for further editing.

3) „Closed visit“: this visit is closed, no further data entry or data correction is allowed.

4) „Approved visit“: The already closed visit is approved by the country PMOS coordinator.

Fill-in rules and guides (1)

There are some signes and rules to support the data entry process.

- The field is obligatory (missing value is not allowed). 1)

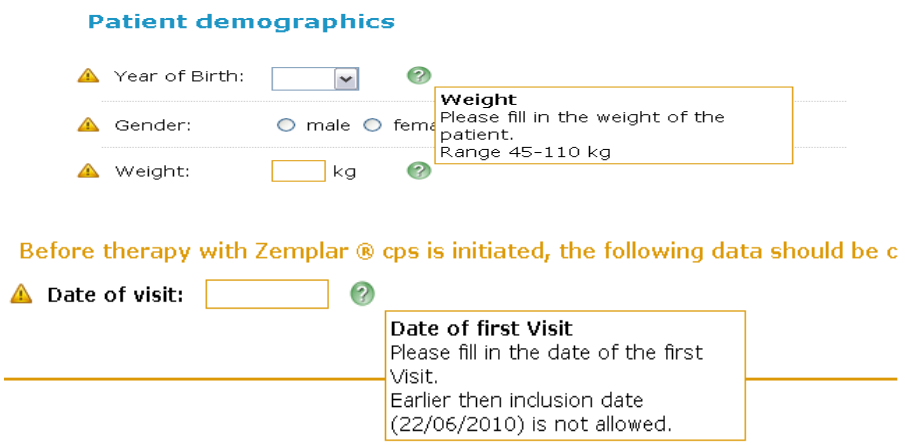
- Move your cursor over the icon to get information about the acceptable values.

a) There are **obligatory** data fields which can not be left empty (1)

b) There are **guides** (2) to support the data entry process. These guides generally give the acceptance ranges of the given variables. 2)

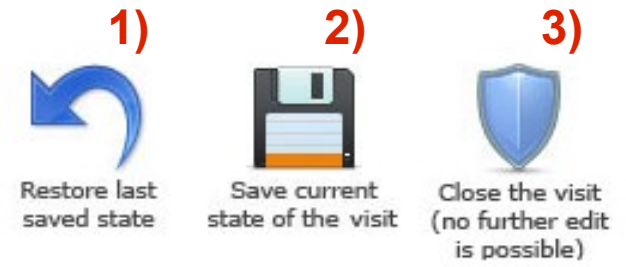
(Acceptance range means a clinically and/or physiologically meaningful range. Within this range all value is automatically accepted. Otherwise a further confirmation is required to enter a value outside of the acceptance range. The acceptance range is not identical with normal ranges.)

Fill-in rules and guides (2)


Patient demographics
Year of Birth:
Gender:
male
Weight:
kg
Weight
Please fill in the weight of the patient.
Range 45-110 kg
Before therapy with Zemplar ® cps is initiated, the following data should be c
Date of visit:
Date of first Visit
Please fill in the date of the first Visit.
Earlier then inclusion date (22/06/2010) is not allowed.

The guide with one or several rules to be fullfilled can contain an acceptance range (1) (see the previous page), or some other rule or restriction for the data to be entered in a certain box (2).

Icons of data entry process



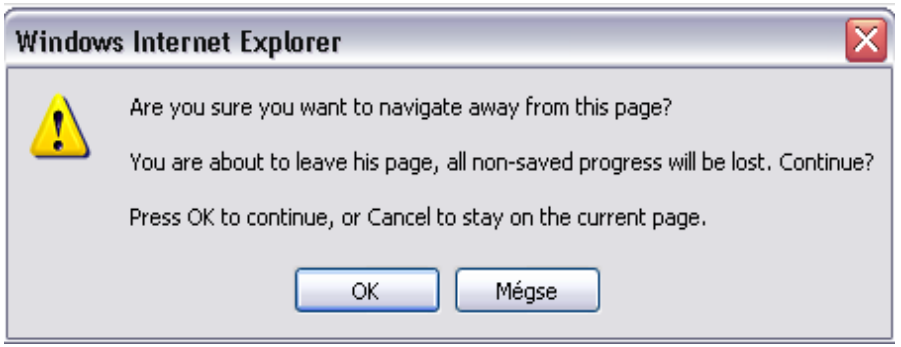
1) This icon is for the restoration of the last saved version of the visit. This button is useful if you would like to restore the last saved state of the visit (ALL changes made after the last save will be LOST)

2) THE ENTERED DATA ARE NOT AUTOMATICALLY STORED ON THE SERVER. YOU HAVE TO SAVE YOUR WORK WITH THIS BUTTON. All saved data of a certain visit are available for further editing TILL CLOSING THE VISIT.

3) AFTER CLOSING THE VISIT, NO FURTHER MODIFICATION IS POSSIBLE on the given subject's visit.

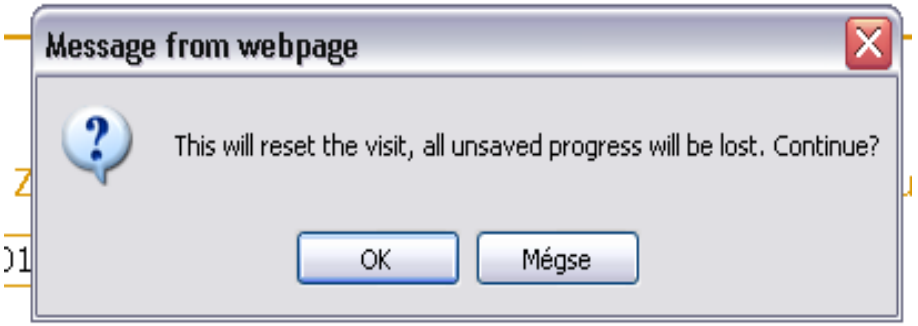
If a visit is closed by accident, or you wish to re-open it for any reason, please make a request for this on the message board (found under Administration > Message board) by writing a detialed description of the issue, including the patient ID and the name of the visit to be opened. An E-mail will be sent to you about the decission of the PMOS. If approved, the visit will be opened for further editing.

Pop-up messages


Windows Internet Explorer
Are you sure you want to navigate away from this page?
You are about to leave his page, all non-saved progress will be lost. Continue?
Press OK to continue, or Cancel to stay on the current page.
OK
Mégse

There are many pop-up messages to avoid the incorrect application of the eCRF, e.g. to avoid leaving a Visit without saving the data by mistake.

Pop-up messages (2)

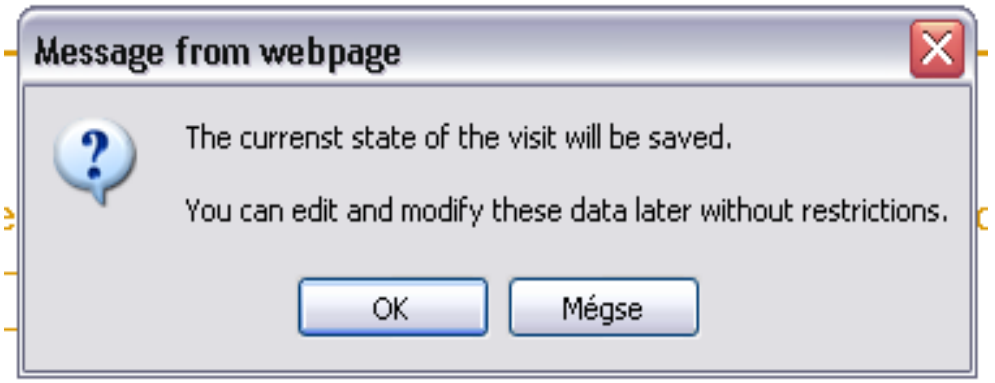


After clicking the

icon this message will be appeared.

- With choosing the “OK” option the last saved visit data of the given patient will be restored. ALL MODIFICATIONS SINCE THE LAST SAVE WILL BE LOST.
- With choosing the “CANCEL” option, no action will be taken.

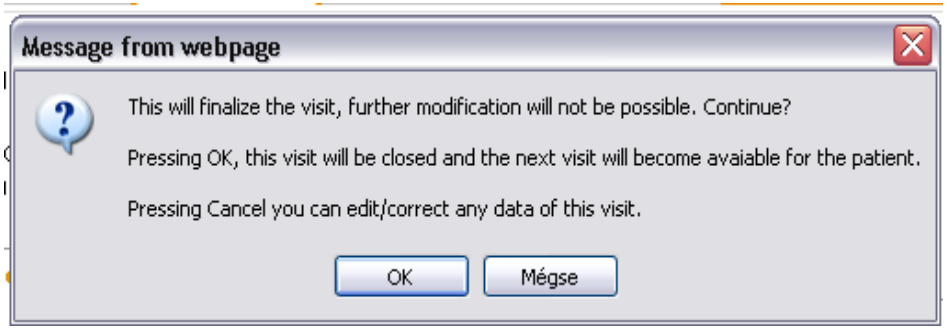
Pop-up messages (3)


Message from webpage
The currenst state of the visit will be saved.
You can edit and modify these data later without restrictions.
OK
Mégse

With clicking the

icon all the data of the actual visit will be saved to the server. All these data will be available for further editing without any restricition.

Pop-up messages (4)

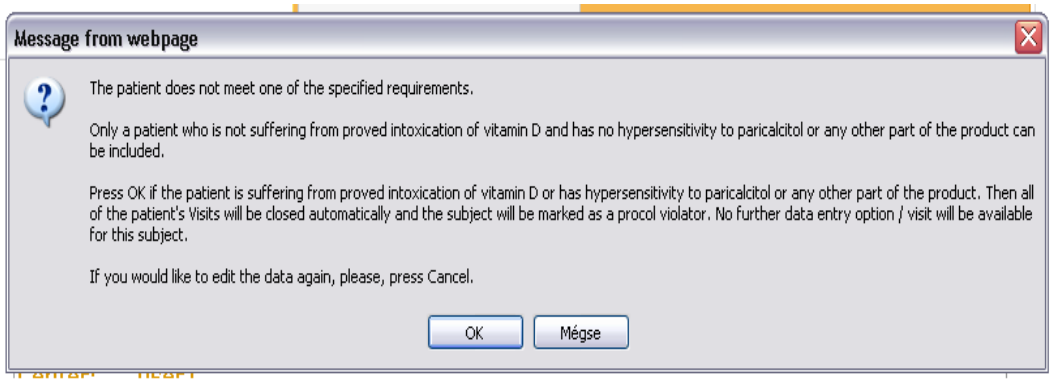

Message from webpage
This will finalize the visit, further modification will not be possible. Continue?
Pressing OK, this visit will be closed and the next visit will become avaiable for the patient.
Pressing Cancel you can edit/correct any data of this visit.
OK
Mégse

With clicking the

icon The current visit (of the current patient) will be saved and closed (in other word: frozen). Further modification of already closed data is not supported by the system.

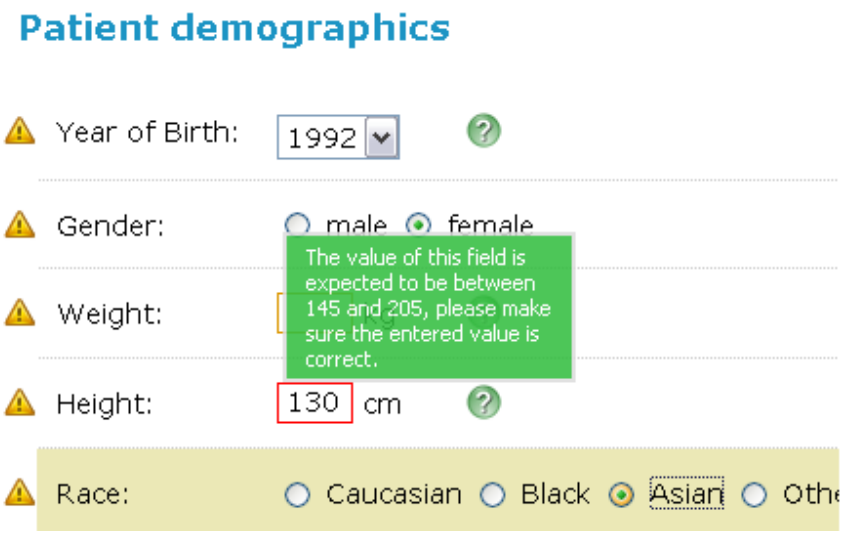
If a visit is closed by accident, or you wish to re-open it for any reason, please make a request for this on the message board (found under Administration > Message board) by writing a detialed description of the issue, including the patient ID and the name of the visit to be opened. An E-mail will be sent to you about the decission of the PMOS. If approved, the visit will be opened for further editing.

Pop-up messages (5)


Message from webpage
The patient does not meet one of the specified requirements.
Only a patient who is not suffering from proved intoxication of vitamin D and has no hypersensitivity to paricalcitol or any other part of the product can be included.
Press OK if the patient is suffering from proved intoxication of vitamin D or has hypersensitivity to paricalcitol or any other part of the product. Then all of the patient's Visits will be closed automatically and the subject will be marked as a procol violator. No further data entry option / visit will be available for this subject.
If you would like to edit the data again, please, press Cancel.
OK
Mégse

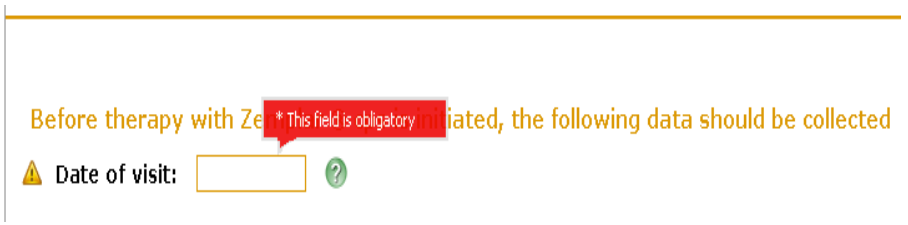
There are special (patient) inclusion rules concerning some specific laboratory (CA and iPTH) data. If the specified laboratory is outside of the range given by the protocol, no inclusion is possible.
In such a case the visit will be closed by the system automatically, and the patient will be excluded from the study.

Other messages



If a value outside of he acceptance range is entered, a message will appear with green background. The message will again show the acceptance range. Clicking into this green box, a confirmation of the value outside of the acceptance range will be accepted by the eCRF, although the red border will indicate the special status of the value.

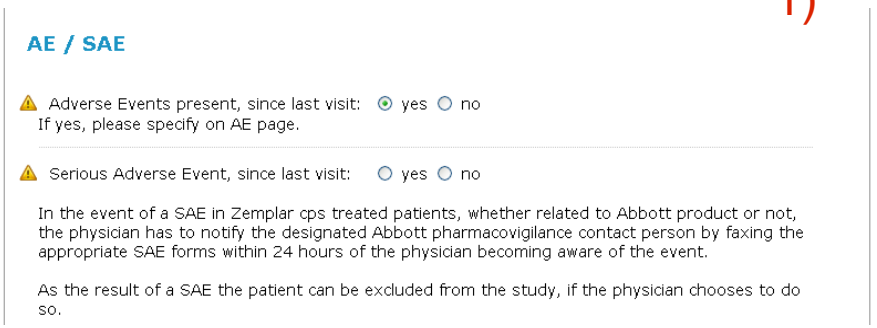
Other messages (2)



Errors which can not be left unsolved are indicated by messages with the red background. These messages generally concern obligatory data (with no data), or for other fill-in rules (e.g. data of the 1st visit can be earlier than the Informed Consent date). You have to click into the message to hide it, but you also have to correct the data or give a value to an obligatory but still empty field.

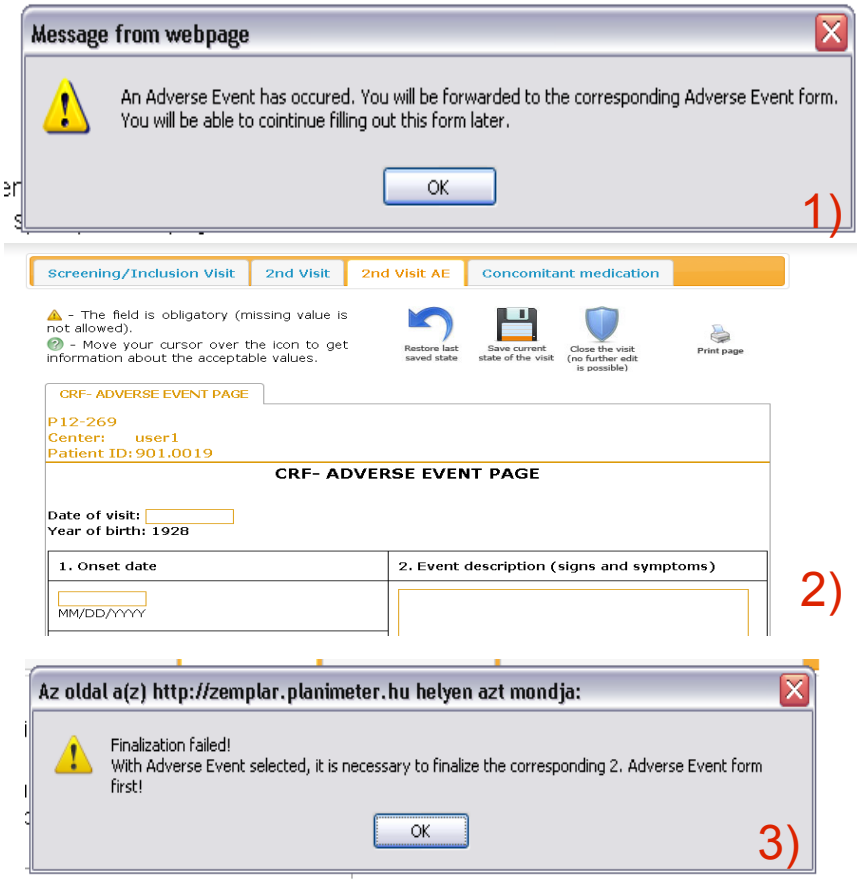
AE/SAE

1)


AE / SAE
Adverse Events present, since last visit: yes no
If yes, please specify on AE page.
Serious Adverse Event, since last visit: yes no
In the event of a SAE in Zemplar cps treated patients, whether related to Abbott product or not, the physician has to notify the designated Abbott pharmacovigilance contact person by faxing the appropriate SAE forms within 24 hours of the physician becoming aware of the event.
As the result of a SAE the patient can be excluded from the study, if the physician chooses to do so.

1) Adverse Event (AE) or Serious Adverse Event (SAE) can be entered from Visit 2.

AE


Message from webpage
An Adverse Event has occured. You will be forwarded to the corresponding Adverse Event form.
You will be able to cointinue filling out this form later.
OK
1)
Screening/Inclusion Visit
2nd Visit
2nd Visit AE
Concomitant medication
- The field is obligatory (missing value is not allowed).
- Move your cursor over the icon to get information about the acceptable values.
Restore last saved state
Save current state of the visit
Close the visit (no further edit is possible)
Print page
CRF- ADVERSE EVENT PAGE
P12-269
Center: user1
Patient ID: 901.0019
CRF- ADVERSE EVENT PAGE
Date of visit:
Year of birth: 1928
1. Onset date
2. Event description (signs and symptoms)
MM/DD/YYYY
2)
Az oldal a(z) http://zemplar.planimeter.hu helyen azt mondja:
Finalization failed!
With Adverse Event selected, it is necessary to finalize the corresponding 2. Adverse Event form first!
OK
3)

1) Reporting an AE the following message will appear.

2) The physician will be guided to AE-page automatically. All fields are required!!

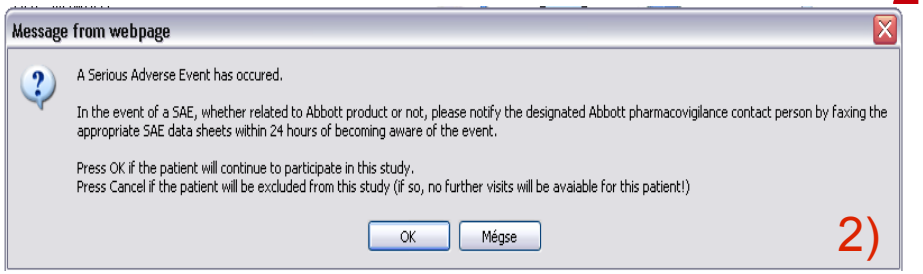
   Multiple AE pages can be created. To create a new AE page, press the “Create new AE page“ button

3) The visit can not be completed if one of the AE forms is not closed.

Serious Adverse Event (SAE)

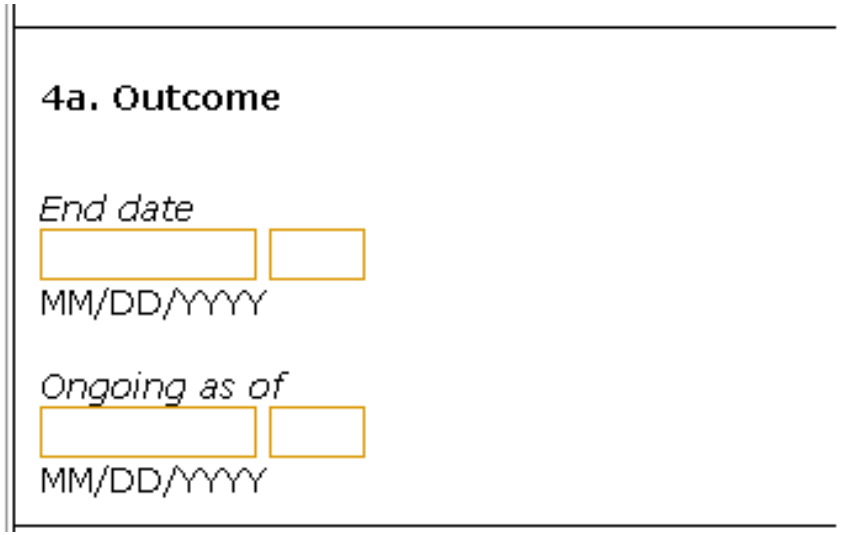
Message from webpage
A Serious Adverse Event has occured.
In the event of a SAE, whether related to Abbott product or not, please notify the designated Abbott pharmacovigilance contact person by faxing the appropriate SAE forms within 24 hours of becoming aware of the event.
OK
1)

1) Ticking the SAE box on the AE-page or visit page the following message will appear.
BE CAREFUL: all SAE should be and will be reported to the local Authority, so you have to give all the SAE-relevant information with utmost care.


Message from webpage
A Serious Adverse Event has occured.
In the event of a SAE, whether related to Abbott product or not, please notify the designated Abbott pharmacovigilance contact person by faxing the appropriate SAE data sheets within 24 hours of becoming aware of the event.
Press OK if the patient will continue to participate in this study.
Press Cancel if the patient will be excluded from this study (if so, no further visits will be avaiable for this patient!)
OK
Mégse
2)

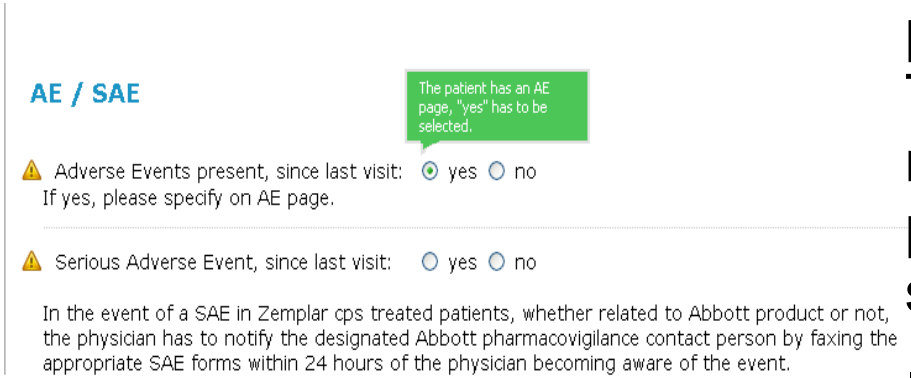
2) Reporting a SAE might result the exclusion from the study.

Filling in of an AE-page



- Each question is obligatory on the AE-page, excluding the cases where the text implies a conditional answer (e.g. information is obligatory if the duration of the AE is less then 24 hours).
- Closing of all AE-pages of a given visit is required to close that specific visit. (Save is naturally still available).
- If an AE is classified as serious then the exclusion of the subject from the study is an available option.

Adverse Event (AE)

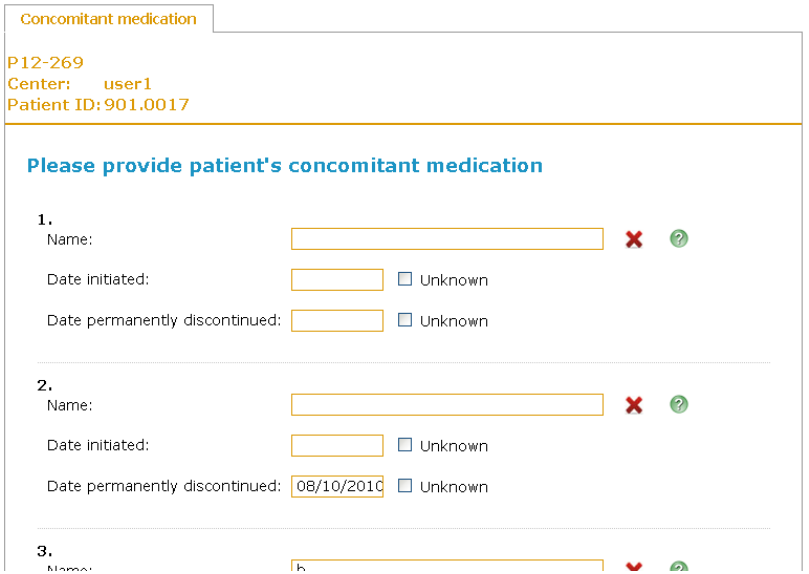

AE / SAE
The patient has an AE page, "yes" has to be selected.
Adverse Events present, since last visit: yes no
If yes, please specify on AE page.
Serious Adverse Event, since last visit: yes no
In the event of a SAE in Zemplar cps treated patients, whether related to Abbott product or not, the physician has to notify the designated Abbott pharmacovigilance contact person by faxing the appropriate SAE forms within 24 hours of the physician becoming aware of the event.

- If there is a reported AE on a Visit, it is indicated with a green message: “Adverse Events present, since last visit”. This AE-status can not be modified. If you would like to perform changes, see the next slide.
- If the AE is classified during the entry of an AE serious (that is the serious box is ticked on the AE-page) then the SAE status will be changed to Yes on the Visit page, too.

AE/SAE indicated by error

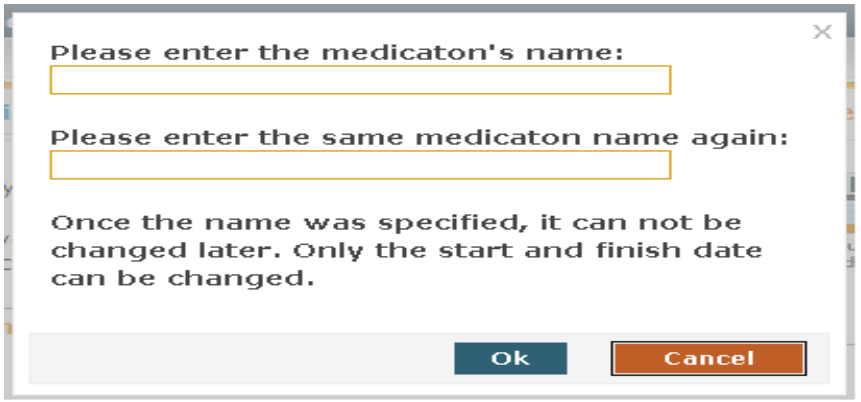
- There is no way of direct modification (deletion) of an AE/SAE entry. If you reported an AE/SAE erroneously, and you would like to make changes or you would like to delete it then:
- You have to send a message via the menu item “Message Board”.
- Your request will be investigated by the local PMOS co-ordinator, and you will be noticed about the applied process and changes by and e-mail.

Concomitant medication 1

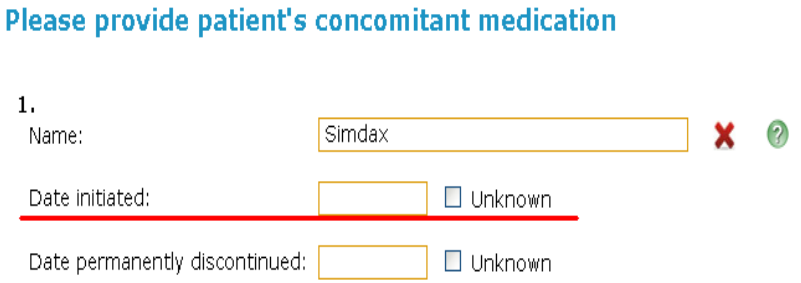


- You have to specify those medications whose administration
  i) had started before the inclusion of the subject and did not stop before inclusion
  ii) started after inclusion

Concomitant medication 2


Please enter the medicaton's name:
Please enter the same medicaton name again:
Once the name was specified, it can not be changed later. Only the start and finish date can be changed.
Ok
Cancel

1)



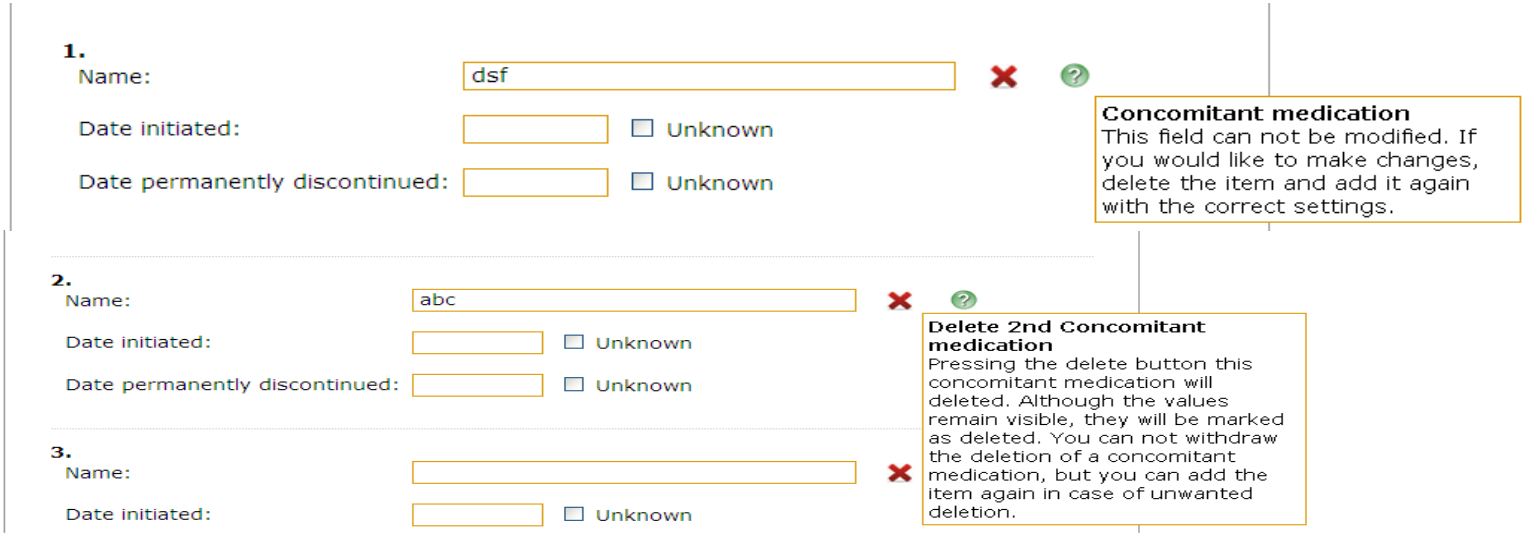
2)

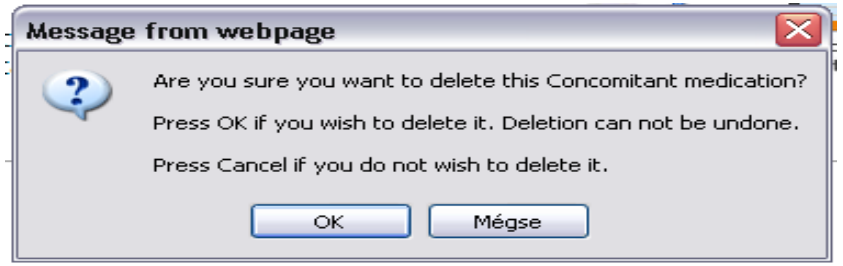
1) Please give the name of the concomitant medication. You have to enter the name twice, and only completely identical entries are accepted. You can not change this name later, but the deletion of an entry is possible.

2) You have to give the start date of the conc. Med. . If the exact date is unknown, please tick the “Unknown” box, and you will get a possibility to enter the starting year and month. If the conc. med. was stopped, the discontinuation date can be given with the application of the previous rules.

3) Discontinuation date can not be earlier than the starting date.

Concomitant medication 3

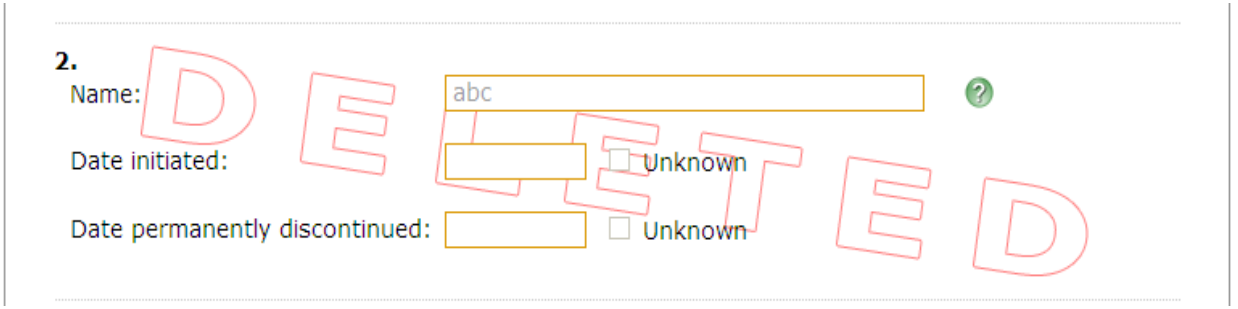

1.
Name:
dsf
Date initiated:
Unknown
Date permanently discontinued:
Unknown
Concomitant medication
This field can not be modified. If you would like to make changes, delete the item and add it again with the correct settings.
2.
Name:
abc
Date initiated:
Unknown
Date permanently discontinued:
Unknown
Delete 2nd Concomitant medication
Pressing the delete button this concomitant medication will deleted. Although the values remain visible, they will be marked as deleted. You can not withdraw the deletion of a concomitant medication, but you can add the item again in case of unwanted deletion.
3.
Name:
Date initiated:
Unknown


Message from webpage
Are you sure you want to delete this Concomitant medication?
Press OK if you wish to delete it. Deletion can not be undone.
Press Cancel if you do not wish to delete it.
OK
Mégse

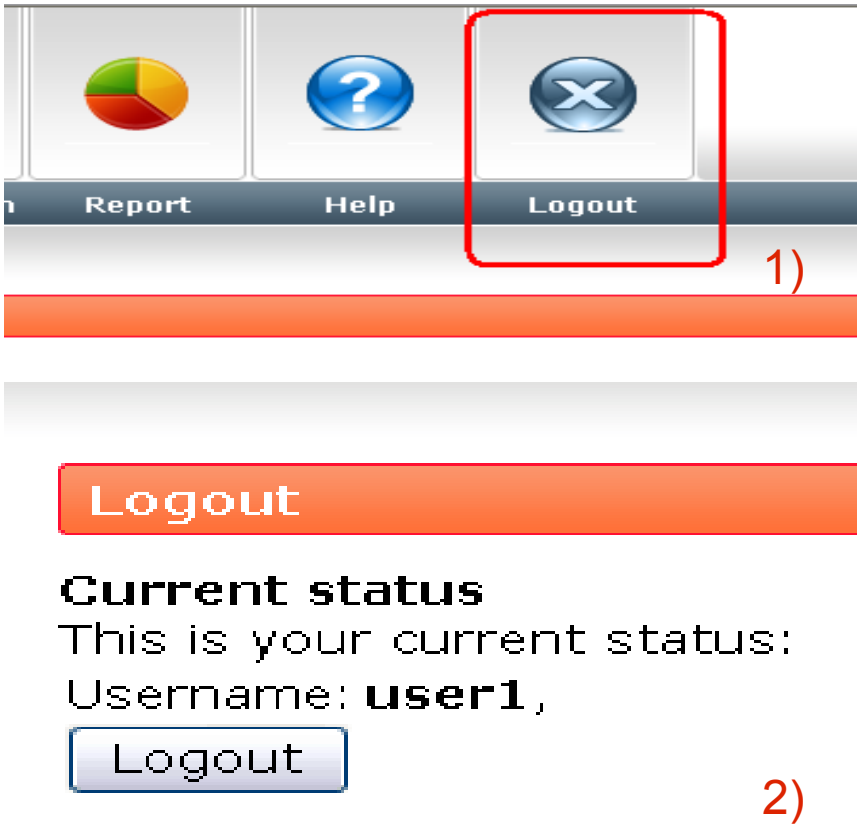
- You can not modify the name of a concomitant medication, but you can delete (with the red X) and add it again in case of erroneous data entry.

Concomitant medication 4

Even the deleted concomitant medication items are displayed – with the watermark: “DELETED” – but no further edition of deleted concomitant medications is supported



Logout



- Choose the “Logout” option (1), then click the logout button (2) to logout.